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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,215	10/16/2001	Janice K. Albrecht	IN01344	5760

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,215	ALBRECHT, JANICE K.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *7/6/4* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In the amendment received August 23, 2004, applicant cancelled claims 1-19 and amended claims 20, 29, 33 and 36. Claims 20-42 are pending and under consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. pre-grant publication no. US 2002/0119122 A1 for reasons of record.

Claims 20-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-70 of U.S. pre-grant publication no. US 2003/0039630 A1 for reasons of record.

Claims 20 and 29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. pre-grant publication no. US 2002/0055473 for reasons of record.

Applicant addresses each of the rejections above separately and states that a terminal disclaimer will be filed to obviate the provisional double patenting rejections upon indication of

allowable subject matter. Until the terminal disclaimers are received, the rejections will be maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Glue et al. (WO 00/37110) for reasons of record.

Applicant states that the instant claims distinguish over the teachings of Glue et al. because the amount of ribavirin instantly administered is based on specific body weight ranges of the patients being treated.

A review of the teachings of Glue has been fully considered, but is found unpersuasive. The instant disclosure defines "therapeutically weight effective amount of ribavirin" as an amount sufficient to produce a sustained virologic response that ranges between twelve to forty-eight weeks post-treatment, see page 4, lines 9-12. The treatment regiment disclosed by Glue et al. induces a sustained virologic response that lasts for at least 24 weeks after the treatment period, see page 3, line 3 to page 4, line 3. Glue et al. anticipate the amount and length of time ribavirin and interferon are administered to patients in the instant claims. Therefore, the

"therapeutically effective amount" of ribavirin administered in the treatment protocol of Glue et al. is equivalent to the "therapeutically weight effective amount of ribavirin" instantly claimed.

Claims 20-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Glue et al. (Hepatology. September 2000; 32 (3): 647-53).

Applicant asserts that the instant claims distinguish over the teachings of Glue et al. because the amount of ribavirin instantly administered is based on specific body weight ranges of the patients being treated. Applicant also points out that Glue et al. administer 1.4 μg/kg of pegylated interferon alfa while the instant claims require 1.5 μg/kg to be administered. Applicant also recites a discussion of Glue et al. regarding the small number of patients in the study and the correlation between anti-viral responses and the ribavirin dose.

Applicant's arguments as well as a review of the reference have been fully considered, but are found to be unpersuasive. The instant claims require "about 1.5 micrograms per kilogram" of pegylated interferon alfa-2b to be administered. The 1.4 μg/kg of pegylated interferon alfa administered by Glue et al. would equate to administering "about 1.5 micrograms per kilogram" recited in the claims. In the passage recited by applicant, Glue et al. is discussing the lack of being able to determine the anti-viral effect of ribavirin. However, the antiviral effect of ribavirin alone is not claimed. Glue et al. clearly show undetectable serum HCV-RNA levels 24 weeks post-treatment in patients that had received the combination therapy, see Figure 3. Therefore, since Glue et al. anticipate the amount and length of time ribavirin and interferon are administered to patients in the instant claims as well as the antiviral effect of the combination therapy, Glue et al. anticipate the "therapeutically weight effective amount of ribavirin" instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (reference AN provided in the IDS) and Gilbert (WO 95/13090) for reasons of record.

Applicant argues that Davis et al. do not teach or suggest the quantities of ribavirin per weight of a patient to be administered as specified by the claims. Applicant also states that there is no direct translation available to convert 3 million units of pegylated interferon alfa to its equivalent in μg/kg. Due to these conclusions, applicant states that the combination of teachings of Davis et al. and Gilbert et al. do not render the invention prima facie obvious.

Applicant's arguments as well as a review of the reference have been considered, but are found unpersuasive. Davis et al. distinguish the differences between weight of a patient and the quantity of ribavirin required to be administered. In other words, Davis et al. identify weight of an individual as a determining factor for the amount of ribavirin to be administered. Therefore, it would have been prima facie obvious for the ordinary artisan to adjust the dose of individual components administered for treatment because it is conventional practice in the vaccine art to optimize dosages, depending on individual factors, such as weight, for each patient. Although there is no conversion available for the different dosage units for interferon alfa, Davis et al. teach that the combination therapy resulted in a sustained virologic response post-treatment, see Tables 2 and 3 as well as the section bridging pages 1494-1495. Therefore, it is determined that

the quantity of interferon used in the combination treatment of Davis et al. is equivalent to the instant dose administered.

Claims 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over McHutchison et al. (reference AM of the IDS) and Gilbert (WO 95/13090) for reasons of record.

Applicant argues that McHutchison et al. do not teach or suggest the quantities of ribavirin per weight of a patient to be administered as specified by the claims. Applicant cites page 1489 in McHutchison et al. and concludes that the reference teaches away from body weight being a contributable factor in sustained virologic response. Applicant also states that there is no direct translation available to convert 3 million units of pegylated interferon alfa to its equivalent in μg/kg. Due to these conclusions, applicant states that the combination of teachings of McHutchison et al. and Gilbert et al. do not render the invention prima facie obvious.

Applicant's arguments as well as a review of the reference have been considered, but are found unpersuasive. McHutchison et al. distinguish the differences between weight of a patient and the quantity of ribavirin required to be administered. In other words, McHutchison et al. identify weight of an individual as a determining factor for the amount of ribavirin to be administered. Therefore, it would have been prima facie obvious for the ordinary artisan to adjust the dose of individual components administered for treatment because it is conventional practice in the vaccine art to optimize dosages, depending on individual factors, such as weight, for each patient. Although there is no conversion available for the different dosage units for interferon alfa, McHutchison et al. teach that the combination therapy resulted in a sustained virologic response post-treatment, see Table 2 and "Virologic Response" bridging pages 1487-1488. With respect to the excerpt cited by applicant, although McHutchison et al. teach that the

virologic response rate after treatment is not attributable to individual patient factors, such as weight, McHutchison et al. clearly indicate that the actual dose tailored to a patient's weight to achieve the virologic response rate after treatment is a critical factor. Since McHutchison et al. achieve a sustained virologic response rate post- treatment period, it is determined that the quantity of interferon used in the combination treatment of McHutchison et al. is equivalent to the instant dose administered.

Claims 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poynard et al. (provided in the IDS as AL) and Gilbert (WO 95/13090) for reasons of record.

Applicant argues that Poynard et al. do not teach or suggest the quantities of ribavirin per weight of a patient to be administered as specified by the claims. Applicant concludes that the reference teaches away from body weight being a contributable factor in sustained virologic response. Applicant also states that there is no direct translation available to convert 3 million units of pegylated interferon alfa to its equivalent in μg/kg. Due to these conclusions, applicant states that the combination of teachings of Poynard et al. and Gilbert do not render the invention prima facie obvious.

Applicant's arguments as well as a review of the reference have been considered, but are found unpersuasive. Poynard et al. distinguish the differences between weight of a patient and the quantity of ribavirin required to be administered. In other words, Poynard et al. identify weight of an individual as a determining factor for the amount of ribavirin to be administered. Therefore, it would have been prima facie obvious for the ordinary artisan to adjust the dose of individual components administered for treatment because it is conventional practice in the vaccine art to optimize dosages, depending on individual factors, such as weight, for each

patient. Although there is no conversion available for the different dosage units for interferon alfa, Poynard et al. teach that the combination therapy resulted in a sustained virologic response 24 weeks post-treatment, see Tables 3 and 4 for example. While Poynard et al. do not correlate virologic response rate after treatment with individual patient factors, such as weight, Poynard et al. clearly indicate that the actual dose tailored to a patient's weight to achieve the virologic response rate after treatment is a critical factor. Since Poynard et al. achieve a sustained virologic response rate post- treatment period, it is determined that the quantity of interferon used in the combination treatment of Poynard et al. is equivalent to the instant dose administered.

Claims 20-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reichard et al. (provided in the IDS as AK) and Gilbert (WO 95/13090) for reasons of record.

Applicant argues that Reichard et al. do not teach or suggest the quantities of ribavirin per weight of a patient to be administered as specified by the claims. Applicant also cites page 108S in Reichard et al. that states that optimal doses of combination therapy have not been discovered. Applicant also states that there is no direct translation available to convert 3 million units of pegylated interferon alfa to its equivalent in μg/kg. Due to these conclusions, applicant states that the combination of teachings of Reichard et al. and Gilbert et al. do not render the invention prima facie obvious.

Applicant's arguments as well as a review of the reference have been considered, but are found unpersuasive. Reichard et al. distinguish the differences between weight of a patient and the quantity of ribavirin required to be administered. In other words, Reichard et al. identify weight of an individual as a determining factor for the amount of ribavirin to be administered. Therefore, it would have been prima facie obvious for the ordinary artisan to adjust the dose of

individual components administered for treatment because it is conventional practice in the vaccine art to optimize dosages, discussed by Reichard et al., depending on individual factors, such as weight, for each patient. Although there is no conversion available for the different dosage units for interferon alfa, Reichard et al. teach that the combination therapy resulted in a sustained virologic response post-treatment, see Tables 1-3 as well as the "Results" section bridging pages 84-85. Therefore, it is determined that the quantity of interferon used in the combination treatment of Reichard et al. is equivalent to the instant dose administered.

Conclusion

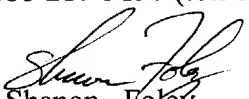
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Primary Examiner
Art Unit 1648